K090929

JUN 12 2009

Chapter III 510(k) Summary

(As required by 21 CFR 807.92)

The assigned 510(k) Number is: _____

1. Date Prepared: March 17, 2009

2. Sponsor Information

Shanghai Double-Dove Industry Co.,Ltd

No.1888 Huhang Road
FengXian Economic Zone
Shanghai, 201400, China

Contact Person: Mr. Sanba Yang, Quality Manager
Tel: +86-21-67104888
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E-Mail: Yangsbmaster@hotmail.com

3. Submission Correspondent

Ms. Diana Hong
Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongshan Zhongxin Mansion
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030, China

4. Device Name and Classification:

a. Sterile Hypodermic Syringe for single use
(1) Classification Name: Syringe, Piston
(2) Regulation Number: 880.5860
(3) Product Code: FMF
(4) Class: II

b. Sterile Insulin Syringe for single use, with fixed needle
(1) Classification Name: Syringe, Piston
(2) Regulation Number: 880.5860
(3) Product Code: FMF
(4) Class: II
(5) Review Panel: General Hospital

c. Sterile Hypodermic Needle for single use
(1) Classification Name: Needle, Hypodermic, Single Lumen
(2) Regulation Number: 880.5570
(3) Product Code: FMI
(4) Class: II
(5) Review Panel: General Hospital

5. Predicate Device Identification:
a. **K number: K980987**
Trade Name: Becton Dickinson Single Use Hypodermic Syringes

b. **K number: K071630**
Trade Name: TERUMO 31G ThinPro Insulin Syringe

c. **K number: K070440**
Trade Name: BD Hypoint

6. Device Description:

TableIII-1 General Description of Applicant Devices

Device Name	Intended Use	Nozzel	Volume	Material	Remark
Sterile Hypodermic Syringe for single use	The Sterile Hypodermic Syringe for Single Use is intended for dispensing/ administering fluids, and collecting/ sampling of fluid in medical practice. Their function is mechanical.	Luer Slip	1ml、3ml、5ml、10ml、20ml、30ml、50ml	Medical Grade Polypropylene	With or Without Needle
		Luer Lock	1ml、3ml、5ml、10ml、20ml、30ml、50ml		
Sterile Insulin Syringe for single use, with fixed needle	The sterile Insulin Syringe for single use with fixed needle is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.	Fixed	0.3ml、0.5ml、1ml	Medical Grade Polypropylene	With Fixed Needle
Sterile Hypodermic Needle for single use	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration	Luer Slip Luer Lock	0.3*12.7; 0.3*25; 0.33*12.7; 0.33*12.7; 0.33*25; 0.4*12.7; 0.4*25; 0.45*16; 0.45*25; 0.5*16; 0.5*25; 0.55*16; 0.55*25; 0.6*25; 0.6*30; 0.7*25; 0.7*32; 0.8*25; 0.8*38; 0.9*25; 0.9*38; 1.1*25; 1.1*38; 1.2*25; 1.2*38	Stainless Steel	--

K080929

7. Test Conclusion

Laboratory testing was conducted to validate and verify that Double-Dove Syringes and Needle met all design specifications and was substantially equivalent to the predicate device.

8. Substantially Equivalent Conclusion:
The subject device, Double-Dove Syringes and Needle, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shanghai Double-Dove Industry Company, Limited
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, No. 19, Lane 999, Zhongshan No.2 Road (S)
Shanghai
CHINA 200030

JUN 12 2009

Re: K090929
Trade/Device Name: Sterile Insulin Syringe for Single Sue Needle, with Fixed Needle
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: March 31, 2009
Received: April 2, 2009

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number:

Device Name: Sterile Hypodermic Syringe for Single Use

Indications for Use:

The Sterile Hypodermic Syringe for Single Use is intended for dispensing/ administering fluids, and collecting/ sampling of fluid in medical practice. Their function is mechanical.

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090929

Indication for Use

510(k) Number:

Device Name: Sterile Insulin Syringe for single sue needle, with fixed needle

Indications for Use:

The sterile Insulin Syringe for single use with fixed needle is a device is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin, and for the injection of insulin into parts of the body below the surface skin.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _√_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090929

Indication for Use

510(k) Number:

Device Name: Sterile Hypodermic Needle for single use

Indications for Use:

The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Division of Anesthesiology, General Hospital
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